Remarks

The final Office Action mailed July 1, 2003 has been received and reviewed. The application is to be amended as previously set forth. All pending claims except claim 27 are to be canceled without prejudice or disclaimer. New claim 51 is to be added. All amendments are made without prejudice or disclaimer. Claim 27 is rejected. Reconsideration is requested.

A. 35 USC § 112, 1st ¶:

The earlier "written description" rejection of the pending claims under 35 USC § 112, first paragraph, was withdrawn in the Office Action. (Paper No. 27, pages 2-3).

The earlier "enablement" rejection under 35 USC § 112, first paragraph, was revised to now apply to claims 1, 18, 20, 22, 27, and 47. (*Id.*, p. 3). Claims 1, 18, 20, 22, and 47 are to be canceled, however, thus obviating the need to respond to the rejection as is pertained to them. Applicants respectfully traverse the remainder of the rejection.

In response to applicants' earlier comments, the Examiner pointed out that as the "claims were not limited to Ad5.fib16luc and methods of using such" and "the claims encompassed any adenoviral vector from subgroup C, not limited to Ad5 [*but, see,* new claim 51], and the fiber knob domain could be any adenoviral fiber knob domain including Ad5 itself, not limited to Ad16", the claims were not thought sufficiently enabled.

Claim 27 is to be amended so that "the fiber of said recombinant adenovirus comprises at least one protein fragment of an adenovirus serotype of subgroup C and at least a knob domain of a fiber protein of a second adenovirus serotype associated therewith [wherein the] second adenovirus serotype [is] selected from the group consisting of serotype 11, serotype 16, serotype 35, and serotype 51". New claim 51 specifically defines the adenovirus serotype of subgroup C to be adenovirus serotype 5, which should certainly overcome a portion of the rejection as regards this claim.

Basis for the amendment is inherent throughout the as-filed application, but specific basis can be found in Figures 17 and 19 and Tables XVI and XVIII (showing that fiber 11 and fiber 35 work well for transducing synoviocytes) and Figures 18A and 18B and Tables XVIIa and XVIIb (showing that fiber 51 is also a good candidate). Thus, no new matter is added.

Applicants respectfully point out that it is not essential that adenovirus serotype 5 be used as a backbone vector to place the fiber knob on top of. Subgroup C is a very useful backbone vector since the members are well known and can be easily produced to high titers on available packaging cells, as are the other members of subgroup C. Other serotypes may encounter problems in that regard. The fiber knob used is what is important to the claimed method of delivering a nucleic acid of interest to the target cells. The prior art is silent about which fiber to use in the claimed method, and the inventors hereof were the first to show that these specific serotypes were highly useful.

Paper No. 27 acknowledged that the claims do not place any structural limitation on the knob domain's relative position and relation. Applicants believe this is appropriate. After reviewing applicants' disclosure, a person of skill in the art can readily determine the knob domain from any known (or new) adenovirus serotype by comparing the fiber amino acid sequences of all known serotypes and by reading the literature about fiber functions. A significant number of articles have been published that deal with the positions of the tail, shaft, and knob domains within the fiber protein. The knob domain can therefore be easily distinguished from the shaft and tail of any known and new serotype.

Applicants assert that the reason that Wickham (US Patent 6,455,314) states that the use of other fiber knobs proved to be "disappointing", was because, previously, workers mainly dealt with replacing the entire fiber, thereby yielding a weak interaction with the penton base. The claimed method does not replace an entire fiber, but utilizes a chimeric fiber, wherein the fiber tail is of the same serotype as the penton base for proper fiber protein function and stabilization.

As previously alluded to, one reason for including other serotypes within the scope of the claims is that the as-filed Specification shows that not only fiber 16 works well, but Figure 17 and Figure 19 and Table XVI and Table XVIII show that fiber 11 and fiber 35 also work well for transduction of synoviocytes. Figure 18A and B and Table XVIIa and b show that fiber 51 is also a good candidate. That these serotypes have not been used *in vivo*, is due to the fact that one can only ethically experiment with a limited number of monkeys. The inventors specifically chose fiber 16 to represent the other B-group viruses that infect synoviocytes sufficiently well.

In view of the foregoing, applicants request that the rejection be withdrawn.

B. 35 USC § 112, 2nd ¶:

Claims 1, 3, 18, 20, 22, 47, and 48 were rejected as assertedly being indefinite under the second paragraph of 35 USC § 112. These claims are to be canceled, however, thus obviating the need to respond to the rejection.

C. 35 USC § 102:

The earlier rejection under 35 USC § 102 over Maxwell was withdrawn. Likewise, the earlier rejections under 35 USC § 102 over Stevenson et al., and Wickham et al. was revised to now only apply to claim 20. As claim 20 is to be canceled, no need remains to respond to the rejections.

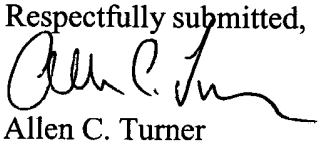
D. 37 CFR § 1.116 and Entry of Amendments:

This amendment should be entered. It merely cancels claims and otherwise places the application in condition for allowance. To the extent the amendment does not place the application in condition for allowance, it certainly removes issues for appeal. No new issues are raised, and no new matter or issues are raised requiring a search should be required.

Conclusion

If questions remain after consideration of the foregoing, the Office is kindly requested to contact applicants' attorney at the address or telephone number given herein.

Respectfully submitted,



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